REMARKS

I. **SUMMARY OF THE OFFICE ACTION**

The office action withdraws all previous rejections. The office action rejects the claims as indefinite under 35 USC 112 and for obviousness under 35 USC 103.

II. **CLAIMS**

Claims 1-5 and 12-41 are pending. Claims 1, 16, 24, 25, 28, 31, 35, and 38 are the independent claims. Independent claims 1, 16, and 24 are substantial analogs of one another. Independent claims 25, 28, and 31 are substantial analogs of one another directed to the novel method of making, composition so made, and method of using - - the disclosed liposome-encapsulated anti-lipase antibody. Claims 35-41 describe the composition, method of making, and method of using the novel composition, by defining the process disclosed in the specification at page 4 lines 9-17 (example 2) used to prepare the liposome - anti-lipase antibody composition. The disclosed liposome - anti-lipase antibody composition is believed to be novel.

III. **REJECTION OF CLAIMS AS INDEFINITE UNDER 35 USC 112**

The office action rejects claim 1, stating that:

> Claim 1's preamble is indefinite in failing to recite what is intended purpose for the claimed method steps provided in the body of the claim, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. [Office action page 3 lines 6-8.]

In response, the applicant notes that claims do not need to recite an intended purpose for the claimed method steps recited in the body of the claim to be definite. A claim only defines subject matter. Moreover, the applicant disagrees that the resulting claim, that is, the body of the claim, is not definite. Claim 1 recites "A method comprising: feeding an animal food and a liposome-encapsulated anti-lipase antibody." The step of "feeding an animal food and a liposome-encapsulated anti-lipase antibody" is clear and definite.

The office action also rejects claim 1 stating that:

Claim 1 is vague and indefinite in reciting, "feeding an animal food and ... antilipase

antibody" because it is unclear as to whether the food and the anti-lipase antibody are in a formed mixture of food; or are the two elements intended to be fed to the animal separately, as recited. [Office action page 3 lines 9-12.]

In response, the applicant submits that the recitation "feeding an animal food and ... antilipase antibody" is clear and definite. That recitation does not recite a step of mixing or mixture, and there is no basis for construing claim 1 to be limited to feeding a mixture. The undersigned notes that I had previously characterized claims 1, 16, and 24 as "substantial analogs" of one another, and that claims 16 and 24 do define mixing or mixture. I apologize if that characterization caused the examiner any confusion.

The office action also rejects claim 3, stating that:

> Claim 3 is confusing in relation to claim 1 from which it depends because claim 1 appears to recite a "method of using [a composition]" claim such as for feeding an animal, whereas the instant claim recites "storing" the composition in a particular state, i.e. wet state or freeze dried, which appears to be encompassed in a "method of forming" claim. Accordingly, it is unclear what structural and functional cooperative relationship exists between the elements of the instant claim and those of claim 1 from which it depends. [Office action page 3 lines 13-19.]

In response, the applicant first notes that claims 1-3 read as follows.

1. (Previously Amended) A method comprising: feeding an animal food and a liposome-encapsulated anti-lipase antibody.

2. (Previously Amended) The method of claim 1 wherein said anti-lipase antibody is an avian antibody.

3. (Previously Amended) The method of claim 2 further comprising at least one of storing said liposome-encapsulated anti-lipase antibody in a wet state and freeze drying said liposome-encapsulated anti-lipase antibody.

The applicant respectfully traverses because the examiner's conclusion that claim 1 is limited to a method of feeding is incorrect. Claim 1 recites in pertinent part "A method comprising: " and the open recitation "comprising" indicates that any other additional steps are

within the scope of claim 1. Therefore, the additional step defined by claim 3 of "storing" is a proper additional limitation to the subject matter defined by claim 1.

The examiner statements regarding claim 3 also imply that method of using and method of making steps in one claim are improper. 35 USC 101 contains no such limitation on method claims, and it defines what is suitable subject matter for method claims. It states as follows:

35 U.S.C. 101 Inventions patentable.

> Whoever invents or discovers any new and useful ***process***, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Thus, there is no statutory basis to reject a claim reciting both method of making and method of using steps.

As to the examiners concerns about a "structural and functional cooperative relationship", such a relationship need not be defined by a claim. However, in the context of the disclosure, clearly storage followed by feeding is disclosed, and are disclosed as useful steps.

The office action also rejects claim 12, stating that:

> Claim 12 is also confusing in relation to claim 1 from which it depends.
>
> Same analogous comments and problems in claim 3 apply to claim 12.
>
> For the reasons stated for claim 3, claim 12 complies with 35 USC 112, second paragraph. [Office action page 3 lines 20-21.]

The office action also rejects claim 17, stating that:

> Claim 17 lacks clear antecedent basis problem in reciting, "said liposome encapsulated avian anti-lipase antibody". [Office action page 3 lines 22-23.]

The applicant first notes that claims 16 and 17 reads as follows.

16. (Previously Presented) A composition, comprising: a mixture of food for an animal and a liposome-encapsulated anti-lipase antibody.

17. (Previously Presented) The composition of claim 16 which contains 25-1000 mg of said liposome-encapsulated avian anti-lipase antibody per kilogram of said food.

In response, the applicant amends claim 17 by deleting "avian." I thank the examiner for

catching the lack of antecedent basis.

The office action objects to claim 23, stating that:

Claim 23 is objected to as being a duplicate of claim 18. [Office action page 4 line 3.]

In response, the applicant amends claim 23 to depend from claim 22. I thank the examiner for identifying the duplicative claims.

The office action rejects claim 35, stating that:

> Claim 35 is indefinite in reciting, "new" because the term "new" is a subjective term that lacks a comparative basis for defining its metes and bounds in relation to the set of claims. [Office action page 4 lines 7-11.]

The office action contains similar reasoning in rejecting claims 36-40.

The applicant first notes that claim 35 reads as follows.

> 35. (Previously Presented) A method of making a composition comprising:
> providing a solution including anti-lipase antibodies; and
> adding liposomes to said solution to make a new solution.

The applicant respectfully disagrees that there is no comparative basis for reciting "new," because there is comparative basis for reciting "new". The comparative basis is the recitation "providing a solution including anti-lipase antibodies" The "new" solution is specified as the result of "adding liposomes to said solution." However, in order to avoid the issue, the applicant amends claim 35 by replacing "a new solution" with "a solution containing said liposomes" in claim 35 and also in claims 36-40.

The office action objects to claim 41, stating that:

> Claim 41 is confusing in relation to claim 38 from which it depends because claim 38 appears to recite a "composition formed by a process" claim, whereas the instant claim recites "feeding said composition to an animal", which appears to be encompassed in a "method of using" claim. Accordingly, it is unclear what structural and functional cooperative relationship exists between the elements of the instant claim and those of claim 38 from which it depends. [Office action page 5 lines 7-12.]

In response, the applicant disagrees. Claim 41 is a conventional method of using a product claim. The product is defined by process of its making. The applicant has however placed claim 41 in independent form in response to the holding in Pfizer, Inc. v. Ranbaxy Laboratories Limited, F.3d 1284; 2006 U.S. App. LEXIS 19416; 79 USPQ2d 1583 (Fed. Cir. August 2, 2006). This is a formal amendment which makes no substantive amendment to the language of claim 41.

IV. THE REJECTIONS OVER PRIOR ART

A. WHAT THE EXAMINER STATED

The examiner rejected claims 1-5 and 12-41 as obvious, stating that:

> 7. Claims 1-5 and 12-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US Patent 5,919,451) in view of Drent et al. (Lipase inhibition: a novel concept in the treatment of obesity, International Journal of Obesity 17: 241-244 (1993)) and in further view of LeClercq et al. (Metabolism of very low density lipoproteins in genetically lean or fat lines of chicken, Reproduction, Nutrition, Development, 30 (6): 701-715 (1990)).
>
> Cook et al. provide a method for improving the growth of an animal and improving efficiency of the animal to convert its feed into desirable lean body tissue. Cook et al. specifically disclose feeding to the animal a food composition comprising a liposome-encapsulated immunoglobulin or antibody that helps protect the animal from disease and/or antigens that can affect the animal's growth and physiology (see column 1, lines 18-23 and column 2, lines 1- 6). The antibodies used in this invention are those that can alter physiological processes that adversely affect growth and feed efficiency or they can be antibodies that provide protection against diseases or against specific endogenous regulators of food intake or gastrointestinal mobility, i.e. lipase (see column 3, lines 5-14). The food composition is made by forming a nutrient mixture and then depositing the liposome-encapsulated antibody into the pellet core (see column 2, lines 12-21). The antibodies may be provided in solution, in an aqueous or lipid carrier, i.e. liposome-encapsulation, and may also be directly applied to the pellet core

without a carrier (freeze-dried) such as a powder. The antibodies are, however, preferably encapsulated in liposome. The antibodies are avian, i.e. obtained from egg of a hen which has been injected with antigen that results to the production of its corresponding antibodies (see column 2, lines 22-46). The food protein and carbohydrate may also include vitamins and dietary lipid (column 2, lines 54-67 and column 4, lines 1-19). Specifically, the food composition containing the avian antibodies is fed to the animals in an amount effective to passively immunize the animal or otherwise enhance the efficiency of feed conversion by the animal (column 1, lines 41-52 and column 3, lines 1-4). Cook et al.'s food composition and method are prepared as animal feed for use in either mammals (pets), or avians such as ducks, chickens, and turkeys (see column 6).

Cook et al. differ from the claimed invention in failing to teach that the antibodies are anti-lipase antibodies, or antibodies directed against lipase antigen.

Drent et al. teach that lipase inhibition is a novel concept in the treatment of obesity. Specifically, Drent et al. teach that by inhibiting gastric and pancreatic lipase, absorption of dietary fat is reduced due to inhibition of triglyceride hydrolysis. Drent et al. tested and confirmed the concept using oral administration of the compound, Orlistat, which is an inhibitor of gastric, carboxylester and pancreatic lipase and which has served useful in weight reduction in humans because of its inhibitional effect on gastrointestinal lipases (see Abstract,, page 241 and page 243, column 2).

Leclercq et al. teach using anti-lipoprotein lipase antibodies to completely inhibit lipoprotein lipase in fat lines and lean lines of chickens (see page 703, column 2 to page 704, column I). At page 705, columr12 to page 706 and page 709, column 2 to page 71 1, LeClercq confirmed that anti-lipoprotein antibodies are able to inhibit lipoprotein lipase activity, and conclude that difference in fatness is not due to difference in feed intake but to metabolic deviations depending on hormonal control.

It would have been obvious to one of ordinary skill in the art at the time of

the instant invention to incorporate the teaching of Drent of oral administration of Orlistat as modified by the teaching of LeClercq of the similar effect by anti-lipase antibodies as Orlistat, into the method as taught by Cook of feeding to animals antibodies that are incorporated into food composition, that are directed against antigen inhibitors and regulators of metabolism in order to effect inhibition or regulation of that particular antigen in the animal because anti-lipase antibodies as taught by LeClercq is seen to effect inhibition of lipase activity as does Drent in teaching use of Orlistat to inhibit same for purposes of weight loss.

Cook et al., LeClercq et al., and Drent et al. do not disclose that the composition contains 25 to 1000 mg of liposome encapsulated anti-lipase antibodies per kilogram of the animal food, as recited in claims 14, 15, 17, and 22.

Cook et al. specifically disclose administering a safe and effective amount of antibody that would help protect the animal from disease or other antigens that can adversely affect animal's growth or the efficiency of the animal to convert feed into desirable body tissue. Therefore, the amount of liposome-encapsulated anti-lipase antibody contained in a food composition should be a safe and effective quantity.

Such ranges of antibody concentrations in food composition, are rendered as s result effective variables, which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233,235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276,205 USPQ 215,218-219 (C.C.P.A. 1980). Since

Applicant has not disclosed that the specific limitations recited in claims 14, 15, 17, and 22 are for any particular purpose or solve any stated problem and the prior art teaches that effective concentrations of antibodies or compounds used may vary according to the animals being fed and/or their characteristics, absent unexpected results, it would have been obvious for one of ordinary skill to discover the safe and effective amounts of antibodies and compounds used for the composition and method disclosed by the prior art by normal optimization procedures.

B. **SUMMARY OF THE APPLICANT'S REASONING**

In summary, the applicant (1) explains why the Cook USP 5,919,451 and the other prior art does not suggest doing what is claimed in this case, and (2) presents additional evidence supporting those explanations. In addition, the applicant provides evidence showing that the Cook USP 5,919,451 is not prior art that is, antedating the Cook USP 5,919,451 patent.

C. **THE TEACHINGS OF THE COOK USP 5,919,451 PATENT**

Cook USP 5,919,451 is directed to a method for improving the growth efficiency or the efficiency of feed conversion of an animal. Title. It discloses (abstract) "feeding the animal feed particles having an inner core of nutrients and an outer layer containing a conjugated fatty acid or an antibody that can protect the animal from contacting diseases...." Cook's Background section describes giving animals antibiotics, immunizing animals, and feeding animals avian antibodies to antigens to prevent intestinal diseases. Cook's Summary of the Invention section states in pertinent part that:

> In a preferred embodiment of the invention, antibodies are provided in solution or suspension in an aqueous or lipid carrier, although the antibodies can be applied directly to the pellet core without a carrier as, for example, a powder. The antibodies can be, but need not be, encapsulated in the lipid.

Cook's Detailed Description section states that:

> The antibodies for use in the present invention are those which can alter physiological processes that adversely affect growth and feed efficiency. They can be antibodies that are against diseases or specific endogenous regulators of food

intake and gastrointestinal motility. The antibodies are preferably derived from the eggs of hens which have been previously immunized to produce those antibodies as described in U.S. Pat. Nos. 4,748,018 or 5,080,895. Especially preferred as the antibody-containing material are spray dried egg yolks and whole eggs. However, other non-egg derived antibody-containing materials may be used.

The only actual antibody disclosed in Cook is antibody to CCK. The only antigen actually discloses in Cook is CCK. See Cook columns 4-6. According to Wikepedia, Cholecystokinin (CCK;)[1] is a peptide hormone of the gastrointestinal system responsible for stimulating the digestion of fat and protein. Cholecystokinin, previously called pancreozymin, is secreted by the duodenum, the first segment of the small intestine, and causes the release of digestive enzymes and bile from the pancreas and gallbladder, respectively. It also acts as a hunger suppressant. See http://en.wikipedia.org/wiki/Cholecystokinin. A copy of http://en.wikipedia.org/wiki/Cholecystokinin is ATTACHMENT 1.

Cook's examples are only for feed including CCK antibodies compared to a control feed. These examples show that feed including the antibody to CCK reduces weight gain (Table 1); and increases feed conversion efficiency (Table 2).

Cook's results are contradictory in that its sole example is an antibody to a protein (CCK) that stimulates digestion of fat and protein. Use of such an antibody would logically decrease digestion of fat and protein leading to decreased feed conversion efficiency. However, Cook's results show increased feed conversion efficiency and weight gain. Cook's results are in accord with its stated goal of feeding "antibodies ... which can alter physiological processes that *adversely* affect growth and feed efficiency..."

Cook does not disclose feeding anti-lipase antibodies. In contrast to Cook, this application discloses feeding liposome-encapsulated anti-lipase antibodies. Cook's stated goal is to inhibit "physiological processes that adversely affect growth and feed efficiency." In contrast to Cook's stated goal, this application discloses that feeding liposome-encapsulated anti-lipase antibodies decrease feed conversion efficiency, and reduce weight gain, and increase weight loss.

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[1]A copy of http://en.wikipedia.org/wiki/Cholecystokinin is ATTACHMENT 1.

This goal is exactly the opposite goal, and exactly the opposite effect, obtained by Cook' liposome encapsulated antibodies to CCK.

D. **THE TEACHINGS OF DRENT**

Drent teaches inhibition of fat absorption resulting from inhibiting gastric and pancreatic lipase activity. Drent teaches that ingestion of Orlistat in humans inhibits gastric and pancreatic lipase, and that one result is reduced absorption of dietary fat due presumably due to inhibition of triglycerides hydrolysis. Abstract.

Orlistat is a drug used to treat obesity: a drug that blocks the intestinal absorption of dietary fats into the bloodstream so that they pass out in the feces. Orlistat is not an antibody, and it is not an anti lipase antibody.

E. **THE TEACHINGS OF LECLERCQ**

LeClercq's teaches that intravenously injecting LPL antibody into chickens suppresses LPL activity in the chickens. LeClercq discloses feeding birds low fat diets. (Animals and Diets section on page 702); preparation of antibodies to LPL (lipoprotien lipase; an enzyme that cleaves a fatty acid from a triglyceride; page 703); intravenous injecting chickens with antibodies to LPL (pages 703-704); and suppression results (remaining pages).

F. **THE COMBINED TEACHINGS OF COOK, DRENT, AND LECLERCQ**

Cook teaches feeding antibody to CCK improves feed conversion efficiency.

Drent is not directed to an antibody, and LeClercq does not disclose ingestion. Drent relates only to a drug, not an antibody, and therefore provides no teaching suggesting efficacy of ingesting antibodies. Thus, Drent provides no teaching relevant to Cook.

LeClercq relates only to the effect of antibodies in the blood, not in the gut. Thus, LeClercq provides no teaching relevant to Cook. Specifically, LeClercq provides no teaching suggesting efficacy of making and feeding anti lipase antibodies.

Accordingly, the teachings of both LeClercq and Drent are unrelated to the teachings of Cook and provide no suggestion of any kind with respect to modifying what Cook discloses.

Further, none of these three reference suggests inhibiting anti lipase, an anti lipase antibody, or ingesting a liposome coated anti lipase antibody. Moreover, none of these references provide a teaching suggesting a reasonable expecation of success of making and

feeding animals antibodies to anti lipase. The only disclosed feeding results are the results for the antibodies produded in response to CCK. The efficaciy of such results does not provide a suggestion or a reasonable expectation of success for any process involving anti lipase. As a result, the rejections are for combinations and modifications of the prior art that are clearly based upon hindsight, and therefore improper, and therefore shoul be reversed.

The office action reasons for combining the three applied references are that:

> It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Drent of oral administration of Orlistat as modified by the teaching of LeClercq of the similar effect by anti-lipase antibodies as Orlistat, into the method as taught by Cook of feeding to animals antibodies that are incorporated into food composition, that are directed against antigen inhibitors and regulators of metabolism in order to effect inhibition or regulation of that particular antigen in the animal because anti-lipase antibodies as taught by LeClercq is seen to effect inhibition of lipase activity as does Drent in teaching use of Orlistat to inhibit same for purposes of weight loss.

The applicant respectfully disagrees because as shown in the prior paragraphs the rejection is objectively based solely upon hindsight. However, consider the examiner's stated rationale for the modifications of the prior art: "in order to effect inhibition or regulation of that particular antigen in the animal because anti-lipase antibodies as taught by LeClercq is seen to effect inhibition of lipase activity as does Drent in teaching use of Orlistat to inhibit same for purposes of weight loss." The alleged motivation "anti-lipase antibodies as taught by LeClercq is seen to effect inhibition of lipase activity" is however only applible, as taught by LeClercq, to the blood. Surely, the effectiveness of an anti body in the blood does not provide a motivation or reasonable expectation of success to feeding that antibody! Moreover, Drent is clearly irrelevant since it does not even deal with an antibody. In contrast to the prior art, claim 1 recites "feeding an animal food and a liposome-encapsulated anti-lipase antibody." Accordingly, the rejections are improper and should be reversed. Accordingly, claim 1 would not have been obvious in view of the applied prior art.

G. SECONDARY INDICIA OF NON OBVIOUSNESS

In Graham, the court indicated that evidence of anything contradicting a prima facie case of obviousness was probative. Two such types of evidence exist in this case. The first is that conclusion of the examiner of the Cook parent patent, USP 5,725,873, that that patent (which is admittedly more limited than the disclosure in the Cook 5,919,451 patent) was only enabling for its CCK example. See the file history of USP 5,725,873. Second, evidence exists in US patents showing the uncertainty in effectiveness of anti bodies generated in eggs in response to anti nutritional factors injected into hens. See USP 6,793,921, USP 5,827,517, and USP 5,989,548.

A copy of the file history of USP 5,725,873 is Attachment 2.[2]

A copy of USP 6,793,921 is Attachment 3.[3]

A copy of USP 5,827,517 is Attachment 4.[4]

A copy of USP 5,989,548. is Attachment 5.[5]

1. The Conclusions Reached by the Examiner of USP 5,725,873 are Contrary to the Obviousness Conclusion Reached by the Examiner in this Application

In the file history of the parent of the Cook patent, USP 5,725,873, the examiner thereof concluded that the disclosure therein of feeding a liposome encapsulated antibody to CCK was not enabling for any substance except liposome encapsulated antibody to CCK. As a result, the originally broad claims in the application resulting in USP 5,725,873 were limited during prosecuction to define only a feed containing antibodies to CCK. More specifically, in that application (which is the parent of the applied Cook patent), the examiner concluded that:

> ...the specification, while being enabling for providing animals with antibody to cholecystokinin (CCK), does not reasonably provide enablement for [broad claims to] passively immunizing an animal against antigens which could reduce the

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[2] A copy of the file history of USP 5,725,873 which is Attachment 2.

[3] A copy of USP 6,793,921 is Attachment 3.

[4] A copy of USP 5,827,517 is Attachment 4.

[5] A copy of USP 5,989,548 is Attachment 5.

animal's ability to grow or to efficiently convert its feed into desirable body tissue. The specification does not enable any person skilled in the art to which 10 it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. *** *Given the-nature of the invention, which is to enhance the digestive process, it would require undue experimentation on the part of a skilled artisan to determine which other antigens that are active in digestive processes would be suitable as targets for antibodies which are administered orally by the method of the present invention.* [Interpolation supplied.]

What this portion of the file history of the Cook parent patent indicates is that Cook's teachings relating to antibidies to CCK do not enable any other types of antibodies. This conclusion is contrary to the conclusion in the office action in this application that the the Cook child patent, which also only has examples of antibodies to CCK, is a suitable basis to legally suggest (which requires a presumption of enablement) feeding antibodies to some other nutritional related factor. As a result, even if the Cook 5,919,451 child patent were prior art, the obviousness rejections based primarily thereon would be improper. However, as shown in the next section, the Cook 5,919,451 patent is not prior art.

The undersigned notes that in the prosecution of the Cook 5,919,451, the continuation in part of the parent Cook patent, Cook was awarded broader claims, claims not expressly limited to CCK. Cook's 5,919,451 is broader that in the Cook parent patent. However, the 112 lack of enablement issue was improperly addressed by the applicant in the file history of the Cook 5,919,451 in two ways. A copy of the file history of the Cook 5,919,451 patent is ATTACHMENT 9.[6] As a result, the Cook 5,919,451 patent's claims should not have issued for the same reason the broad claims originally filed by Cook in the application that issued into USP 5,725,873 did not issue.

First, Cook asserted the fact that his parent application, the application that issued into the Cook USP 5,725,873, was allowed as a reason to withdraw enablement rejections in the

[6]A copy of the file history of the Cook 5,919,451 patent is ATTACHMENT 9.

application that issued into Cook 5,919,451. See the file history of the Cook 5,919,451 paper 7, Amendment A, third and fourth (unnumbered) pages; pages 59 and 60 of the file history. A copy of the file history of the Cook 5,919,451 patent is ATTACHMENT 9. That was improper because the only claim allowed in the application that issued into the Cook USP 5,725,873 was the claim limited to CCK.

Second, Cook cited the existence of WO 96/04933, stating that that PCT publication was "of record, wherein a number of suitable gut peptides known to those skilled in the art are described for use in a related method." However, WO 96/04933 is another one of Cook's early works with CCK. It is entitled "CCK Antibodies Used to Improve Feed Efficiency". All of its studies and results are for CCK. It contains no assertion that its inventors invented anything other than its CCK inventions. What it does state is the hypothesis that, "by generating antibodies to peptides, hormones, and cytokines, ect., that regulate biochemical, metabolic, and Physiological, and/or behavioral processes, *it may be possible* to regulate or alter an animal's system to compensate for a physical abnormality or accentuate a normal function." Page 8 lines 18-23; italics added. It "suggests" that "similar responses could be achieved ... [for] gastrin... somatostatin, ...bombesin... [and] neuropeptide Y...." Paragraph spanning pages 8 and 9. In other words, the WO 96/04933 provides mere speculation about possible inventions. Perhaps motivation to experiment, but not a reasonable expectation of success. Motivation to experiment is insufficient to provide legal obviousness:

> The PTO presents, in essence, an "obvious to experiment" standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. Interconnect Planning Corporation v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). Of the many scientific publications cited by both Dow and the PTO, none suggests that any process could be used successfully in this three-component system, to

produce this product having the desired properties. [In re Dow Chemical Co., 837 F.3d 469, ___, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988).]

Moreover, as described in the next section in this response, most of the specific compounds that were subject to the speculation in WO 96/04933 *failed in fact* to provide the desired effect, as illustrated by subsequent work. This is objective evidence that there was no reasonable expectation of success for antibodies to compounds other than CCK, from the Cook disclosures.

A copy of WO 96/04933 is ATTACHMENT 10.[7]

2. **There is Additional Objective Evidence Supporting the Conclusion Efficacy of Feeding AntiBodies to CCK to affect metabolism did not Provide a Reasonable Expectation of Success for any Other Nutrition related Factor**

Objective evidence indicates that the examiner's conclusions on lack of enablement were soundly based. That evidence is the result of tests presented in USP 6,793,921 and USP 5,827,517 showing no efficacy for antibodies to certain other nutrition related factors. That test data shows that some of the antibody treatments were effective, and some were not effective. USP 5,827,517 reports in its example 9 (spanning columns 9 and 10) on the feeding of *antibodies* to Bombesin, Motilin, and Neuropeptide Y. (Note the title of example 9: "Feeding Anti-Peptides to Broiler Chicks". The example 9 results at column 10 lines 50-55 refer to the peptides, which appears to be short hand for the tested anti peptides.) Of those three, only antibodies to Neuropeptide Y had an effect on weight gain or feed conversion efficiency differing from the control group. Thus, anitbodies to all but one of the nutritional factors tested in USP 5,827,517, failed to show any effect. Moroever, that is despite the strong effect the actual nutritional factors had on weight gain or feed conversion efficiency noted in USP 5,827,517's example 12 at columns 13 and 14.

Similarly, USP 5,989,548 shows that feeding anitbodies to Bravo provided no substantial

[7]A copy of WO 96/04933 is ATTACHMENT 10.

effect compared to the control group. See USP 5,989,548 example 11 in columns 11 and 12.

Similarly, USP 6,793,921 also shows the unpredictability in this area of technology. It states that:

> The present invention was made based on the above discovery suggesting that antibodies against whole cells of Hp are not sufficient and antibodies against urease of Hp and/or flagella of Hp are effective for completely inhibiting the colonization of Hp in gastric mucosa to inhibit the growth of Hp in the stomach. It was further found that the combination of each or both of these antibodies and at least one organism selected from lactic acid bacteria, Enterococcuses, yeasts and Bacillus has a synergistic effect.

The point of this disclosure is that "antibodies against whole cells of Hp [H. pylori ; a bacteria in the lining of the stomach] are not sufficient " indicating that an antibody to yet another factor present in digestive systems was ineffective.

Julio Pimentel, inventor of this application, agrees with the interpretation of USP 5,827,517, USP 5,989,548, and USP 6,793,921. Julio Pimentel 37 CFR 1.132 declaration stating that interpretation is ATTACHMENT 7.[8]

Keep in mind that US patents tend to report only successful experiments - those supporting patentable inventions. Hence, the fact that USP 5,827,517, USP 5,989,548, and USP 6,793,921 evidence failed experiments using anitbodies suggests that other researchers tried and failed on antibodies to yet digestive and nutritional related substances for which results do not appear in other US patents. In any case, the evidence presented here shows that the art was very uncertain as to what antibodies, if any, to nutritional factors, other than CCK, would show an effect. As a result, the showing in USP 5,919,451 that feeding antibodies to CCK had an effect, objectively did not provide a reasonable expectation of success for feeding of antibodies to any other nutritional factor, such as antibodies to the claimed anti lipase.

FURTHER EVIDENCE: On 12/27/2006, upon reviewing the draft of this filing, the undersigned

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[8]A 37 CFR 1.132 declaration of Julio Pimentel stating his interpretation of cited patents is ATTACHMENT 7.

noted a facsimile from inventor Pimentel dated 12/12/2006 in which Dr. Pimentel provided abstracts of two additional relevant studies. A copy of the FAX from Dr. Pimentel containing abstracts of two additional studies is ATTACHMENT 11.[9] This FAX was in response to a verbal request from the undersigned to Dr. Pimentel requesting Dr. Pimentel to review the literature and provide to the undersigned any additional publications showing that the results of ingestion of antibodies was uncertain. It does not represent a complete list of studies showing results of studies of ingestion of antibodies. As of this date, 12/27/2006, the undersigned was informed by an Anitox telephone receptionist that Dr. Pimentel is on vacation, and therefore the undersigned cannot define the scope of Dr. Pimentel's review. However, both abstracts in ATTACHMENT 10 report on experimental use of antibodies apparently generated using Hen eggs, and apparently ingested, and which failed to achieve the intended effects. Moreover, the first Abstract (Effect of egg yolk anitobidy on experimental Cryptosproidium perfringens colonization in gastrointestinal tract or broiler chickens") indicates additional adverse effects (increased "intestional lesion scores"). Thus, ATTACHMENT 11 evidences both the lack of certainty of efficacy for ingestion of antibodies generated via hen eggs to a particular antigen, but also the lack of certainty as to detrimental side effects. Thus, ATTACHMENT 11 is additional obective evidence supporting the conclusion that there would be no reasonable expectation of success for the claimed invention at the time the claimed invention conceived or reduced to practice by Dr. Pimentel.

Attachment 12 is a copy of a FAX from Dr. Pimentel dated 12/18/2006 providing background information available apparently as of the 2005 year noted on the bottom of some of the pages of this FAX relating to anti nutritional factors. The undersigned includes the information in case the examiner considers it relevant to any issue raised in this amendment merely as a precaution to ensure compliance with rule 56.

H. **ANTEDATING THE COOK USP 5,919,451 PATENT**

The Cook 5,919,451 patent is not prior art. The inventor of the instant application originally filed substantially the same disclosure as contained herein, in an earlier filed application, application 08/888,202 filed July 7, 1997. Due to ownership diversity of claimed

[9] A copy of the FAX from Dr. Pimentel containing abstracts of two additional studies is ATTACHMENT 11.

subject matter, this application was filed separate from the 08/888,202 application, even though that earlier application disclosed substantially the same subject matter relating to liposome coated antibodies to anti lipase as this application. The applicatoin that issued into USP 5,919,451 was filed March 10, 1998, and therefore USP 5,919,451 is not prior art to this application.

A copy of the specification of 08/888,202 filed July 7, 1997 is attached as ATTACHMENT 6.[10]

A 37 CFR 1.131 declaration of the inventor Julio Pimentel, attesting to the specification of 08/888,202 being filed July 7, 1997, and that he is the inventor of both that application and this application, is ATTACHMENT 8.[11]

The following table shows the support in the speciication of 08/888,202 for what is claimed in this application.

CLAIM IN THIS APPLICATION	SUPPORT IN 08/888,202, citations to page and line numbers in ATTACHMENT 5
1. A method comprising: feeding an animal food and a liposome-encapsulated anti-lipase antibody.	Page 1 lines 14-16. Example 7-10 spanning pages 10-12.
2. (Previously Amended) The method of claim 1 wherein said anti-lipase antibody is an avian antibody.	Example 1 spanning pages 5 and 6.

[10]A copy of the specification of 08/888,202 filed July 7, 1997 is attached as ATTACHMENT 6.

[11]A 37 CFR 1.131 declaration of the inventor Julio Pimentel, attesting to the specification of 08/888,202 being filed July 7, 1997, and that he is the inventor of both that application and this application, is ATTACHMENT 8.

3. (Previously Amended) The method of claim 2 further comprising at least one of storing said liposome-encapsulated anti-lipase antibody in a wet state and freeze drying said liposome-encapsulated anti-lipase antibody.	Example 7 spanning pages 10 and 11.
4. (Previously Amended) The method of claim 1 wherein said animal is a mammal.	Page 1 lines 5-10 (field of the invention).
5. (Previously Amended) The method of claim 1 wherein said animal is an avian.	Page 15 lines 4-5 (claim 1).
6-11. (Canceled).	
12. (Previously Presented) The method of claim 1 further comprising forming said liposome-encapsulated anti-lipase antibody prior to said feeding.	Page 10 lines 15-16.
13. (Previously Presented) The method of claim 1 wherein said animal food comprises dietary lipid.	-
14. (Previously Presented) The method of claim 1 wherein said animal food comprises 25 to 1000 mg of said liposome-encapsulated anti-lipase antibody per kilogram of animal food.	-

15. (Previously Presented) The method of claim 1 wherein said animal food comprises at least 25 mg of said liposome-encapsulated anti-lipase antibody per kilogram of animal food..	Page 11 line 15 (750 mg/KG).
16. (Previously Presented) A composition, comprising: a mixture of food for an animal and a liposome-encapsulated anti-lipase antibody.	Page 11 line 15 (750 mg/KG).
17. (Currently Amended) The composition of claim 16 which contains 25-1000 mg of said liposome-encapsulated [[avian]] anti-lipase antibody per kilogram of said food.	Page 11 line 15 (750 mg/KG).
18. (Previously Presented) The composition of claim 16 wherein said anti-lipase antibody is an avian anti-lipase antibody.	Example 1 pages 5-6.
19. (Previously Presented) The composition of claim 16 wherein said liposome-encapsulated anti-lipase antibody is in one of a wet state and a freeze dried state.	Example 7 spanning pages 10 and 11.
20. (Previously Presented) The composition of claim 16 wherein said food is food for a mammal.	Page 1 lines 5-10 (field of the invention).
21. (Previously Presented) The composition of claim 16 wherein said food is food for an avian.	Page 15 lines 4-5 (claim 1).

22. (Previously Presented) The composition of claim 16 wherein said food comprises dietary lipid.	-
22. (Previously Presented) The composition of claim 16 wherein said food comprises at least 25 mg of said liposome-encapsulated anti-lipase antibody per kilogram of animal food.	Page 11 line 15 (750 mg/KG).
23. (Currently Amended) The composition of claim [[16]] 22 wherein said anti-lipase antibody is an avian anti-lipase antibody.	Example 1 pages 5-6.
24. (Previously Presented) A method of making a composition, said composition comprising a mixture of food for an animal and a liposome-encapsulated anti-lipase antibody, said method comprising: forming said liposome-encapsulated anti-lipase antibody; mixing said liposome-encapsulated anti-lipase antibody with said food.	See claims 1 and 17.
25. (Previously Presented) A composition comprising a liposome-encapsulated anti-lipase antibody.	See claim 1.

26. (Previously Presented) The composition of claim 25 wherein said anti-lipase antibody is an avian anti-lipase antibody.	See claim 3.
27. (Previously Presented) The composition of claim 25 wherein said liposome-encapsulated anti-lipase antibody is in a freeze dried state.	See claim 19.
28. (Previously Presented) A method of making a liposome-encapsulated anti-lipase antibody comprising: forming said anti-lipase antibody; and encapsulating said anti-lipase antibody with liposomes to form said liposome-encapsulated anti-lipase antibody.	See claim 1.
29. (Previously Presented) The method of claim 28 wherein said anti-lipase antibody is an avian anti-lipase antibody.	See claim 3.
30. (Previously Presented) The method of claim 28 further comprising freeze drying said liposome-encapsulated anti-lipase antibody.	See claim 19.

31. (Previously Presented) A method of using a liposome-encapsulated anti-lipase antibody comprising: feeding said liposome-encapsulated anti-lipase antibody to an animal.	See claim 1.
32. (Previously Presented) The method of claim 31 wherein said anti-lipase antibody is an avian anti-lipase antibody.	See claim 3.
33. (Previously Presented) The method of claim 31 further comprising freeze drying said liposome-encapsulated anti-lipase antibody.	See claim 19.
34. (Previously Presented) The method of claim 31 further comprising mixing said liposome-encapsulated anti-lipase antibody with food for said animal.	See claim 1.
35. (Currently Amended) A method of making a composition comprising: providing a solution including anti-lipase antibodies; and adding liposomes to said solution to make ~~a new solution~~ a solution containing said liposomes.	See Example 7 spanning pages 10 and 11.

36. (Currently Amended) The method of claim 35 further comprising freezing said ~~new solution~~ solution containing said liposomes.	See claim 19.
37. (Currently Amended) The method of claim 35 further comprising freeze drying said ~~new solution~~ solution containing said liposomes.	See claim 19.
38. (Currently Amended) A composition formed by a process comprising: providing a solution including anti-lipase antibodies; and adding liposomes to said solution to make ~~a new solution~~ solution containing said liposomes.	See Example 7 spanning pages 10 and 11.
39. (Currently Amended) The composition of claim 38 wherein said process further comprises freezing said ~~new solution~~ solution containing said liposomes.	See claim 19.
40. (Currently Amended) The composition of claim 38 wherein said process further comprises freeze drying said ~~new solution~~ solution containing said liposomes.	See claim 19.

41. (Currently Amended) A method of using [[the]] a composition ~~of claim 38~~ formed by a process comprising: providing a solution including anti-lipase antibodies; and adding liposomes to said solution to make a solution containing said liposome encapsulated anti-lipase antibodies; and ~~further~~ comprising feeding said composition to an animal.	See Example 7 spanning pages 10 and 11.

Under relevant law, common disclosure in copending applications supports both conception and constructive reduction to practice. Moreover, the experiments evidenced in the 08/888,202 also show actual reduction to practice of what is now claimed. Examples 1-6 show successful production and use of antibodies to anti lipase. Examples 7-10 show that experiments actually using liposome encapsulatd antibodies to anti lipase were effective for their intended purpose. See the 131 declaration of Julio Pimentel. These are actual reductions to practice having a date not later than the filing date of the 08/888,202 application. Accordingly, the 08/888,202 application antedates the applied Cook patent as to the pending claims. As a result, the obviousness rejections are shown to be improper because that are not based upon prior art.

For the reasons presented above, the subject matter defined by independent claims 1, 16, 24, 25, 28, 31, 35, 38, and 41 would not have been obvious to one of ordinary skill in the art at the time these inventions were made. Accordingly, all of these claims should be allowed.

While the dependent claims define additional limitations which each may be non-obvious over prior art, no reason exists to explore those issues in view of the foregoing conclusions.

A summary of the attachments submitted with this response in support of this response is as follows.

A copy of http://en.wikipedia.org/wiki/Cholecystokinin is ATTACHMENT 1.

A copy of the file history of USP 5,725,873 to Cook is ATTACHMENT 2.

A copy of USP 6,793,921 is ATTACHMENT 3.

A copy of USP 5,827,517 is ATTACHMENT 4.

A copy of USP 5,989,548. is ATTACHMENT 5.

A copy of the specification of 08/888,202 filed July 7, 1997 is attached as ATTACHMENT 6.

A 37 CFR 1.132 declaration of Julio Pimentel stating his interpretation if cited patents is ATTACHMENT 7.

A 37 CFR 1.131 declaration of the inventor Julio Pimentel, attesting to the specification of 08/888,202 being filed July 7, 1997, and that he is the inventor of both that application and this application, is ATTACHMENT 8.

A copy of the file history of the Cook 5,919,451 patent is ATTACHMENT 9.

A copy of WO 9604933 is ATTACHMENT 10.

A copy of a fax from inventor Julio Pimentel containing abstracts of two studies is ATTACHMENT 11.

A copy of a FAX from Dr. Pimentel dated 12/18/2006 providing background information available apparently as of the 2005 year noted on the bottom of some of the pages of this FAX relating to anti nutritional factors is ATTACHMENT 12.

Truly,

12/27/2006
DATE

/RichardNeifeld#35,299/
Richard A. Neifeld
Attorney of Record
Reg. No.: 35,299

RAN

Date/time code: December 27, 2006 (12:18pm)

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